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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,852	11/07/2000	Andrey Zarur Jury	S1417/7004	9828
7590 01/05/2007 Timothy J Oyer Wolf Greenfield & Sacks PC 600 Atlantic Avenue Boston, MA 02210			EXAMINER	
			REDDING, DAVID A	
			ART UNIT	PAPER NUMBER
·			1744	
	<del></del>	·		
SHORTENED STATUTO	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MC	ONTHS	01/05/2007	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

- <del></del>		Application No.	Applicant(s)			
		09/707,852	JURY ET AL.			
	Office Action Summary	Examiner	Art Unit			
		David A. Redding	1744			
Period fo	The MAILING DATE of this communication app r Reply	ears on the cover sheet with the o	orrespondence address			
WHIC - Exten after: - If NO - Failur Any n	CORTENED STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DAISIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing at patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 20 Oc	<u>ctober 2006</u> .				
2a)⊠	This action is <b>FINAL</b> . 2b) This action is non-final.					
	Since this application is in condition for allowar					
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Dispositi	on of Claims					
4)🛛	Claim(s) 157-174 is/are pending in the applicat	tion.				
4	4a) Of the above claim(s) is/are withdrav	vn from consideration.				
5)[	Claim(s) is/are allowed.					
6)⊠	Claim(s) <u>157-162,165 and 168-174</u> is/are rejec	ted.				
·	Claim(s) <u>163,164,166 and 167</u> is/are objected					
8)∐	Claim(s) are subject to restriction and/or	r election requirement.				
Application	on Papers					
9)□ -	The specification is objected to by the Examine	r.				
10) 🔲 -	The drawing(s) filed on is/are: a)☐ acce	epted or b) objected to by the I	Examiner.			
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
	Replacement drawing sheet(s) including the correcti	•				
11) 🔲 -	The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority u	nder 35 U.S.C. § 119					
	Acknowledgment is made of a claim for foreign ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 119(a)	-(d) or (f).			
	1. Certified copies of the priority documents					
	2. Certified copies of the priority documents					
	3. Copies of the certified copies of the prior	•	ed in this National Stage			
* 9	application from the International Bureau ee the attached detailed Office action for a list of		d			
3	ee the attached detailed Office action for a list of	or the certified copies not receive	· .			
Attachment	` •	. 5				
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da				
3) 🔯 Inform	nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date 10/20/06.	5) Notice of Informal P 6) Other:				

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 174,158-160,169-171, are rejected under 35 U.S.C. 102(e) as being anticipated by WO 99/55827.

Figure 1 shows a small reactor (18) comprising a plastic substrate having a plurality of reaction units (6) constructed to operate in parallel, each unit comprising an inlet connected to chamber (9), an outlet connected to waste chamber (10) with a fluid pathway therebetween, the pathway including a chamber (2) having a surface suitable for cell growth (page 7, lines 8-15; page 8, lines 7-14) and a volume less than 1 ml. The reaction unit (6) includes structure in the form of pillars (15) which defines a wall in the chamber and is considered to function as a membrane.

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The pillars (15) allows fluid surrounding the cells to flow to an enclosure (3) positioned proximate the posts (15). The reaction units (6) comprise inlets which are considered to be structurally connectable to a source of nutrients for the cells having a controlled pH. Further the reference discloses that the pillars (15) allows the fluid supporting cells to move beyond the pillars, which in the examiners opinion would include cell interaction products as claimed. See page 4, lines 25 thru page 8, line 15.

Claims 174,157-162,165,168, are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,184,029 (Wilding et al.).

Wilding et al. discloses a device comprising two reaction units (10, 112), each reaction unit comprising inlets (structure leading into elements (14, 1140, outlets (structure leading out of elements (116, 119), a fluid pathway established between the inlets and outlets of the units (10, 112). The units (10, 112) including at least one chamber (14, 16, 114, 119) having a volume of less than 1ml and capable of supporting cell growth. The chamber (14, 16, 114, 119) being fluidly connected to an inlet (56) which is considered capable of being connected to a source for cells having a controlled pH. One unit (10) is shown with a membrane (18) capable of operating as claimed and in flow communication with an enclosure (59b, or 57). The reference further discloses the use of pressure sensors (59a, 59b), temperature sensors (95) and means for controlling temperature. See col. 4, lines 1-7; col. 7, line 62 thru col.8, lines 12; col. 9, lines 5-55. The device is disclosed as being comprised of plastic or glass substrate which is considered capable of supporting cells growth.

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### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 169-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,184,029 B1 (Wilding et al.).

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960 the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.). Accordingly, in the absence of unexpected results it would have been obvious to one skilled in the art to provide the number of reaction units claimed.

#### Response to Arguments

Applicant's arguments concerning the 35 U.S.C. 112, second paragraph rejections in the Office Action mailed 7/17/06 are persuasive.

Regarding the rejection in view of WO 99/55827 applicant argues that the WO reference does not teach a membrane but instead discloses structure in the form of pillars. It is the examiners opinion that the disclosed pillars are the functional equivalent of a membrane since the pillars form a barrier to the flow of cells while allowing the passage of liquid (see page 5, lines 21-26).

Regarding the rejection in view of Wilding et al. applicant argues that the reference does not teach or suggest a chamber constructed and arranged to maintain and cultivate cells in culture, a membrane defining at least one wall of a fluid pathway comprising the chamber, and an enclosure as claimed.

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A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Exparte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). While features of an apparatus may be recited either structurally or functionally, claims<directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429,1431-32 (Fed. Cir. 1997). Applicant is correct that Wilding et al. does not teach cell culturing. However, Wilding et al. does disclose a device having all of the *structural* elements claimed and is considered to be inherently capable of functioning as claimed.

### Allowable Subject Matter

Claims 163,164,166,167, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action.

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In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran-Piazza can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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David A Redding Primary Examiner Art Unit 1744

DAR